3/8/99

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

Food and Drug Administration
555 Winderley Place, Suite 200
Maitland, Florida 32751

m2429n HFI-35

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

WARNING LETTER

FLA-99-38

February 25, 1999

Fred Godbold
Corporate Officer
Bama Sea Products
185 S.E. 13th Avenue
St. Petersburg, Florida 33701-5636

Dear Mr. Godbold:

On November 2, 1998, the Food and Drug Administration (FDA) conducted an inspection of your fish importing facility, located at 1800 N.W. 96th Avenue, Miami, Florida 33172. The investigator, Maria A. Medina, documented, for the second consecutive time this year, serious deviations from the seafood importing regulations in Title 21 Code of Federal Regulations, Part 123 (21 CFR 123). The existence of these deviations causes the fish products being imported and stored by your firm to be adulterated within the meaning of section 402(a)(4) of the Federal Food, Drug and Cosmetic Act (the Act). The following deficiencies were noted:

> Failure to have and implement written verification procedures to ensure that the seafood products were handled in accordance with the requirements of 21 CFR § 123.12(a)(2); and
>
> Failure to adequately perform one or more of the affirmative steps listed in 21 CFR § 123.12(a)(2)(ii) to verify that the seafood products are processed in accordance with the provisions of the HACCP regulations.

The above identified deviations are not intended to be an all inclusive list of deficiencies at your facility. It is your responsibility to ensure that all seafood products processed and distributed by your firm are in compliance with the Act and all requirements of the federal regulations.

You should take prompt measures to correct these deviations. Failure to promptly correct the deviations noted may result in regulatory action without further notice including seizure and/or injunction. In addition, FDA may detain your imported seafood products without examination until your firm is fully in compliance with the Seafood HACCP regulation.

Please notify this office in writing, within fifteen (15) working days of receipt of this letter, of the specific steps you have taken to correct these violations, including an explanation of each step taken to prevent their reoccurrence. Your response should include copies of any available documentation demonstrating that corrections have been made. If corrections cannot be completed within 15 working days, state the reason for the delay and the time frame within which the corrections will be completed.

Your written reply should be directed to Carlos I. Medina, Compliance Officer, Food and Drug Administration, 6601 Northwest 25th Street (P.O. Box 59-2256) Miami, Florida 33159-2256.

Sincerely,

Douglas D. Tolen
Director, Florida District